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| 10/071,395      | 02/08/2002  | Michael L. Bell      | 2030-045            | 9989             |

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| EXAMINER |
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YU, MELANIE J

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| ART UNIT | PAPER NUMBER |
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1641

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05/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/071,395

Applicant(s)

BELL, MICHAEL L.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2 and 4-26 is/are pending in the application.
- 4a) Of the above claim(s) 5-11 and 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 4, 12-14, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's amendment filed 19 March 2007 has been entered.

#### ***Claim Objections***

2. Claims 2, 4 and 12-14 are objected to because of the following informalities:  
dependent claims should not depend from independent claims that are numerically after the dependent claims. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless--

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 25 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Nagasawa et al. (US 6,897,021).

Nagasawa et al. teach a method of providing a plurality of supports, wherein for each of multiple target analytes to be assayed, a solid support is provided which comprises a bound binding ligand capable of specifically binding to the target analyte (col. 2, lines 47-55; col. 8, lines 3-9; col. 8, lines 52-57; col. 13, lines 7-14); using the supports for detection of analyte in a sample, wherein the sample is incubated in the presence of the supports (sample is labeled and allowed to flow over the chip to bind to the receptive material, col. 1, lines 31-37; reactive probe chips are used for detection of analyte in a sample, col. 13, lines 7-14, and would therefore use the detection method described in the "background of the invention" section); and the presence of each of the target analyte to be

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assayed is determined by determining the extent of binding between the target analyte and the solid support bound binding ligand (detection of fluorescence is detected and quantified, col. 1, lines 34-36). Nagasawa et al. do not specifically teach the support providing a steric interference that hinders the ability to bind the binding ligand, but does not hinder the binding of other target analytes to other binding ligands. However, the specification at page 17 describes that beads preferably have a pore diameter of 50 nm and made of controlled pore glass to provide this limitation. Nagasawa et al. teach that the pore size may be 50 nm (example 3, col. 10) and the porous material is controlled pore glass (example 3, col. 10), and therefore provide, or is capable of providing, the steric interference as recited by instant claims 25 and 26.

With respect to claims 2 and 26, the pore size of Nagasawa et al. are the same as the pore size taught in the instant specification for steric interference and therefore the pores of Nagasawa et al. are capable of providing the same steric interference as that recited in the instant claims.

Regarding claim 4, Nagasawa et al. teach the support being a controlled pore glass (col. 8, lines 61-67).

With respect to claims 12 and 13, Nagasawa et al. teach detection in the presence of a detectably labeled ligand-binding molecule and determining the presence of the label, wherein the label is a fluorescent label (col. 1, lines 31-39).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nagasawa et al. (US 6,897,021) in view of McHugh (Flow Microsphere Immunoassay for the Quantitative and Simultaneous Detection of Multiple soluble analytes, Methods in Cell Biology, pgs. 575-595).

Nagasawa et al. teach a method for assaying target analyte by determining binding between the target analyte and the ligand for the target analyte and incubating with a label, but fail to teach detection by flow cytometry.

McHugh teaches a flow cytometry assay (587, Heterogeneous Noncompetitive FMIA for the detection of antibody to antigen X, step 7) wherein the extent of binding between a target analyte and a binding ligand bound to a solid support comprises: binding a ligand bound to the solid support to a target analyte (pg. 576, first paragraph; pg. 581, passive (noncovalent) coating and passive coating; pg. 587, heterogeneous noncompetitive FMIA for the detection of antibody to antigen X, step 1); incubating the solid support in the presence of a detectably labeled binding ligand-binding molecule (pg. 576, last sentence-pg. 577, first sentence; pg. 587, Heterogeneous Noncompetitive FMIA for the detection of antibody to antigen X, steps 5-6); and determining the presence of the detectable labeled binding ligand binding bound to the solid support ligand of the target analyte (587, Heterogeneous Noncompetitive FMIA for the detection of antibody to antigen X, step 7-8), in order to detect multiple analytes in a single sample.

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Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Nagasawa et al., incubation the analyte and binding ligand with a detectable labeled binding ligand-binding molecule and determining the presence of the detectable label using flow cytometry as taught by Sato et al., in order to provide a more sensitive detection of the target analyte.

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 2, 4, 12-14, 25 and 26 have been considered but are moot in view of the new ground(s) of rejection. The previous rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendment requiring a plurality of solid supports for multiple target analytes.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1641



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